

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

TALECRIS BIOTHERAPEUTICS, INC.  
and BAYER HEALTHCARE LLC,

Plaintiffs,

v.

BAXTER INTERNATIONAL INC., and  
BAXTER HEALTHCARE CORPORATION,

Defendants.

BAXTER HEALTHCARE CORPORATION

Counterclaimant,

v.

TALECRIS BIOTHERAPEUTICS, INC., and  
BAYER HEALTHCARE LLC.,

Counterdefendants.

C.A. No. 05-349-GMS

Demand for Jury Trial

**REPLY TO DEFENDANTS' COUNTERCLAIMS TO PLAINTIFFS' AMENDED AND  
SUPPLEMENTAL COMPLAINT**

Plaintiffs and Counterdefendants Talecris Biotherapeutics, Inc. ("Talecris") and Bayer Healthcare LLC ("Bayer") (collectively, "Plaintiffs"), through their respective counsel, as and for their Reply to the counterclaims of Defendant and Counterclaimant Baxter Healthcare Corporation ("Baxter HC") and Defendant Baxter International Inc. ("Baxter Int'l") (collectively, "Baxter") allege as follows:

**REPLY TO BAXTER HC'S COUNTERCLAIM**

**THE PARTIES**

1. Upon information and belief, admitted that Baxter HC is a corporation organized and existing under the laws of the State of Delaware. Talecris and Bayer are without knowledge or information sufficient to form a belief as to the truth of Baxter HC's remaining averments and therefore deny the same.

2. Admitted.

3. Admitted that Bayer is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at 511 Benedict Avenue, Tarrytown, New York 10591. Except as expressly admitted, the averments of this paragraph are denied.

**JURISDICTION AND VENUE**

4. Admitted that defendant Baxter HC attempts to plead an action under the Patent Laws of the United States and that this Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338, 2201 and 2202. Except as expressly admitted, the averments of this paragraph are denied.

5. Admitted.

6. Admitted.

**THE CONTROVERSY**

7. Denied.

8. Admitted that Bayer is part of a worldwide pharmaceutical company having different divisions, including a Biological Products division. Except as expressly admitted, the averments of this paragraph are denied.

9. Talecris and Bayer are without knowledge or information sufficient to form a belief as to the truth of Baxter HC's averments and therefore deny the same, except they admit that one of the products relevant to this action is Baxter HC's intravenous human immune globulin product GAMMAGARD® Liquid.

**A. *Intravenous Immunoglobulins***

10. Talecris and Bayer are without knowledge or information sufficient to form a belief as to the truth of Baxter HC's averments and therefore deny the same.

11. Talecris and Bayer are without knowledge or information sufficient to form a belief as to the truth of Baxter HC's averments and therefore deny the same, except admitted that GAMMAGARD® Liquid is manufactured in liquid form, rather than powder form, *inter alia*, for ease of administration and for other reasons.

12. Admitted that a controversy between Baxter HC and Talecris exists relating to Baxter's GAMMAGARD® Liquid product and the process by which it is made. Except as expressly admitted, the averments of this paragraph are denied.

**B. *The '191 Patent***

13. Admitted that United States patent application serial number 08/532,211, which issued as U.S. Patent No. 6,686,191 ("the '191 patent"), was filed on or about September 22, 1995, and that the '191 patent issued on February 3, 2004 and was assigned to Bayer. Admitted

that the named inventor on the '191 patent is William R. Alonso. Except as expressly admitted, the averments of this paragraph are denied.

14. To the extent this paragraph states a legal conclusion, no response is required. As phrased, the paragraph is denied except admitted that Gamimune 5% and 10% S/D embody certain claims of the '191 patent.

**1. Failure to Disclose Material References**

15. Denied.

**2. Failure to Disclose Material Prior Use**

16. Denied.

**3. Omission of Material Data Showing Solvent/Detergent Treatment Does Not "Always" Increase ACA Levels, As Defined By the '191 Patent**

17. Denied.

18. Admitted.

19. Admitted that the '191 patent speaks for itself. Except as expressly admitted, the averments of this paragraph are denied.

20. Denied.

**a) Failure to Disclose That Solvent/Detergent Treatment Using The Detergent, Tween, Did Not Always Increase ACA Levels**

21. Denied.

**b) Failure to Disclose That pH 5.8 Treatment Did Not Always Increase ACA Levels**

22. Denied.

**4. Dr. Alonso Relied Heavily On "Outlier" Values To Support His Prosecuted Claims**

23. Denied.

24. Denied.

25. Denied.

26. Denied.

27. Admitted that Baxter HC contends that an actual and justiciable controversy exists between the parties regarding the infringement, validity, and enforceability of the '191 patent. Admitted that Baxter HC seeks a judicial determination that it does not infringe any valid and enforceable claim of the '191 patent and that the '191 patent is invalid and unenforceable. . Except as expressly admitted, the averments of this paragraph are denied.

**FIRST CLAIM FOR RELIEF**

**(DECLARATORY JUDGMENT OF NONINFRINGEMENT  
OF THE '191 PATENT)**

28. Talecris and Bayer incorporate by reference as if fully set forth herein each of their replies to paragraphs 1 through 27.

29. Admitted that Talecris and Bayer contend that Baxter HC and others infringe claim 7 of the '191 patent and, upon information and belief, that Baxter HC contends that it does not infringe any valid claim of the '191 patent. Admitted that Baxter HC contends that an actual controversy has arisen and now exists between Counterclaimant Baxter HC and Counterdefendants Talecris and Bayer with respect to Baxter HC's infringement of one or more claims of the '191 patent. Except as expressly admitted, the averments of this paragraph are denied.

30. Admitted that a judicial determination of the respective rights of Talecris, Bayer, Baxter HC, and Baxter Int'l with respect to infringement of claim 7 of the '191 patent pursuant

to 28 U.S.C. §§ 2201 and 2202 is necessary and appropriate under the circumstances. Except as expressly admitted, the averments of this paragraph are denied.

**SECOND CLAIM FOR RELIEF**

**(DECLARATORY JUDGMENT OF INVALIDITY OF THE '191 PATENT)**

31. Talecris and Bayer incorporate by reference as if fully set forth herein each of their replies to paragraphs 1 through 30.

32. Admitted that Talecris and Bayer contend that the '191 patent is valid and, upon information and belief, that Baxter HC contends that the '191 patent is invalid. Admitted that Baxter HC contends that an actual controversy has arisen and now exists between Counterclaimant Baxter HC and Counterdefendants Talecris and Bayer with respect to validity of the '191 patent. Except as expressly admitted, Talecris and Bayer deny the averments of this paragraph.

33. Admitted that a judicial determination of the respective rights of Talecris, Bayer, Baxter HC, and Baxter Int'l with respect to the validity of the '191 patent is necessary and appropriate under the circumstances. Except as expressly admitted, the averments of this paragraph are denied.

**THIRD CLAIM FOR RELIEF**

**(DECLARATORY JUDGMENT OF UNENFORCEABILITY OF THE '191  
PATENT)**

34. Talecris and Bayer incorporate by reference as if fully set forth herein each of their replies to paragraphs 1 through 33.

35. Admitted that Talecris and Bayer contend that the '191 patent is enforceable and, upon information and belief, that Baxter HC contends that the '191 patent is unenforceable.

Admitted that Baxter HC contends that an actual controversy has arisen and now exists between Counterclaimant Baxter HC and Counterdefendants Talecris and Bayer with respect to enforcement of the '191 patent. Except as expressly admitted, Talecris and Bayer deny the averments of this paragraph.

36. Admitted that a judicial determination of the respective rights of Talecris, Bayer, Baxter HC, and Baxter Int'l with respect to the enforceability of the '191 patent is necessary and appropriate under the circumstances. Except as expressly admitted, the averments of this paragraph are denied.

#### **REPLY TO BAXTER HC'S PRAYER FOR RELIEF**

Talecris and Bayer deny that Baxter is entitled to any relief whatsoever, including the relief that Baxter HC requests in its counterclaims.

#### **FIRST AFFIRMATIVE DEFENSE**

1. Baxter's Counterclaim fails to state a claim upon which relief can be granted.

#### **SECOND AFFIRMATIVE DEFENSE**

2. Talecris and Bayer repeat and reallege the allegations of their Amended and Supplemental Complaint. The claims of the '191 patent are valid and enforceable in all respects, and infringed by Baxter.

#### **TALECRIS' AND BAYER'S PRAYER FOR RELIEF**

**WHEREFORE**, Talecris and Bayer request that this Court enter judgment in favor of Talecris and against Baxter as follows:

1. A judgment that Baxter's GAMMAGARD® Liquid [Immune Globulin Intravenous (Human)], 10%, is made according to the processes claimed in the '191 patent, and that its importation into the United States and/or its offer for sale, sale, and/or use in the United States infringes claim 7 of the '191 patent;

2. A judgment permanently enjoining Baxter from making, using, selling, offering to sell, and importing into the United States GAMMAGARD® Liquid [Immune Globulin Intravenous (Human)], 10%, prior to the expiration date of the '191 patent;

3. A judgment permanently enjoining Baxter from inducing infringement of the '191 patent prior to the expiration date of the '191 patent;

4. A judgment permanently dismissing with prejudice all counterclaims of Baxter HC;

5. A judgment awarding Talecris and Bayer damages for Baxter's infringement of the '191 patent;

6. A judgment that Baxter's infringement is willful and awarding Talecris and Bayer treble damages;

7. Attorneys' fees in this action under 35 U.S.C. § 285;

8. Costs and expenses in this action; and

9. Such further and other relief as this Court may deem just and proper.



Respectfully submitted,  
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*Of Counsel for Counterclaim*  
*Defendant Bayer Healthcare LLC*

DATED: June 20, 2007

*Attorneys for the Plaintiffs and*  
*Counterclaim Defendants*

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**CERTIFICATE OF SERVICE**

I hereby certify on this 20<sup>th</sup> day of June, 2007 I electronically filed the foregoing REPLY TO DEFENDANTS' COUNTERCLAIMS TO PLAINTIFFS' AMENDED AND SUPPLEMENTAL COMPLAINT with the Clerk of Court using CM/ECF which will send notification of such filing to the following:

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I also hereby certify that a true copy of the foregoing document was served upon the following in the manner indicated on June 20th, 2007.

<b><u>Via Hand Delivery and E-Mail</u></b> Philip A. Rovner, Esquire Potter Anderson & Corroon LLP Hercules Plaza P. O. Box 951 Wilmington, DE 19899 (302) 984-6140 provner@potteranderson.com	<b><u>Via Federal Express and E-Mail</u></b> Susan Spaeth, Esquire Townsend and Townsend and Crew LLP 379 Lytton Avenue Palo Alto, CA 94301-1431 (415) 576-0200 smspaeth@townsend.com
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